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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/585,925 | 06/02/2000 | Paul Rafferty | BBC-048A | 6299 |

7590 11/23/2004
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EXAMINER

HABTE, KAHSAI

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/585,925

Applicant(s)

RAFFERTY ET AL.

Examiner

Kahsay Habte, Ph. D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-26 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 16-26 and 36-38 are pending.

Response to Amendment

2. Applicant's amendment filed 6/3/2004 in response to the previous Office Action (3/3/2004) is acknowledged. Rejections of claims 16 and 36 under 102(b) and under 103(a) have been obviated by adding proviso and arguments, however, Applicants' amendments in response to this Office Action and the previous Office Action introduces new issue that requires further rejection. The 112 2nd paragraph issue "substituted with suitable substituents" has been maintained.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-26 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 16, it has been recited a proviso to exclude 54 compounds, but there is no descriptive support for this proviso. Applicants drew the chemical structures of these prior art compounds or recited the

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nomenclature to avoid prior art. There were only three provisos as the claim originally filed (see page 162 in the original claim set). Even a negative limitation requires description, *Ex Parte Grasselli*, 231 USPQ 393.

Note that Examiner Hong Liu has raised this issue previously (see Paper No. 21).

The examiner recommends that applicants delete the new provisos and amend the claim to overcome the rejections, e.g. $Q = N$, or define R instead of the broad language. Since there is a lot of prior art, applicants have to recite clearly all the substituents of R and R¹. For example, R¹ is phenyl substituted by the alkyl, alkoxy, etc.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al. (JP 61229874). Cited reference discloses a compound of interest: 2,-[(4-methoxyphenyl)methylene-4-methyl-2H-1,4-benzothiazin-3(4H)-one that is useful for the vasodilator diltiazem. Said compound is almost the same as the excluded compound: 2,-[(4-methoxyphenyl)methylene-2H-1,4-benzothiazin-3(4H)-one when applicant's compound has the following substituents:

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$n = 0$, R = phenyl (aromatic) substituted by methoxy, Q = C, $R^2 = H$, and X = oxygen.

The only difference between applicant's compound and Otsuka's compound is that Otsuka's compound contains a methyl group on the benzothiazine ring (i.e. the ring nitrogen of the benzothiazine ring is N-CH₃). Applicant's excluded compound has -NH instead. Such a variation is considered obvious because of the close structural similarity. See *In re Hoeksema*, 154 USPQ 169; *Ex parte Weston*, 121 USPQ 428; *Ex parte Bluestone*, 135 USPQ 199; *In re Doebel*, 174 USPQ 158. Note also *In re Jones*, 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to *prima facie* obviousness"; one of those listed is "adjacent homologues and structural isomers". Similar is *In re Schechter and LaForge*, 98 USPQ 144, 150, which states "a novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds." Note also *In re Deuel* 34 USPQ2d 1210, 1214 which states, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

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The examiner has attached also the abstract of Otsuka et al. (JP 61229874) from STN print out for applicant's convenience.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-26 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 16, the phrase "R² is....a substituent" is indefinite. What substituent? What is covered and what is not?

b. In claim 16, the phrase "suitable substituents" is indefinite. What is covered and what is not? Applicants have to recite the substituents in order to overcome this rejection, assuming there is support in the specification for said substituents. Note that the definitions of said term is very important, since the core structure when Q = C is known in the art.

Response to arguments

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Applicant's argument filed 06/03/2004 has been fully considered but it is not persuasive.

Applicants argue that the support for "suitable substituents" can be found at page 17, lines 6-9, *inter alia*, of the instant application, but said page of the instant application does not mention what "suitable substituents" cover.

c. In claim 16 (page 5, one line from the bottom), the second chemical structure does not fall within the scope of claim 16. There is no nitrogen atom at 4-position in the core structure.

d. In claim 16 or elsewhere in the claims, the terms "aliphatic" or "aromatic" is not clear. Aliphatic what? Fat acids? Hydrocarbons? Applicants have to recite all the substituents of said terms assuming they have support in the specification. For example, for aliphatic or aromatic it is unclear what are covered and what are not. The same is true for "aromatic". What does aromatic in claim 16 cover? Is "aromatic" substituted or unsubstituted? Is phenyl and naphthyl covered? What about phenol? What about para-chloro phenyl? Note that the definitions of said terms are very important, since the core structure is known in the art.

e. In claim 16 or elsewhere in the claims, the phrase "substituted aliphatic group" is indefinite. In the absence of the specific moieties intended to effectuate modification by the substitution or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicants

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fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

f. In claim 16 (page 2), the phrase "when X is O and n is 0, R¹ is hydrogen" is not clear. How can R¹ is hydrogen when "n" becomes 0? The parenthesis includes both N-R¹, thus if n = 0, R¹ can't be hydrogen. R¹ can be hydrogen only when n = 1. The parenthesis should be shorter for R¹ to be hydrogen when n = 0.

g. In claim 16, the compounds that are excluded and the definition of the variables R and R¹ is not clear. For example, the first excluded compound contain morpholine ring, but morpholine is not permitted by R or R¹ or there is no indication that the aralkyl group is substituted by a heterocycle.

Allowable Subject Matter

5. The following is a statement of reasons for the indication of allowable subject matter: According to the search, the examiner did not find any prior art when Q is N.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

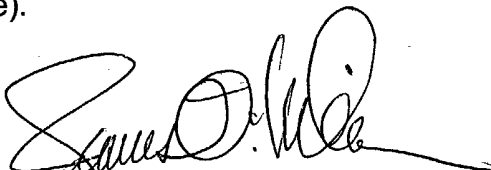
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kahsay Habte, Ph. D.
Examiner
Art Unit 1624

KH
November 18, 2004



James O. Wilson
Supervisory Patent Examiner
Art Unit 1624